**PT Survey Submission and Error Investigation Orientation**

**Name:­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

This is a summarized training document explaining the process of completing the Survey Companion Document and the Survey Error Investigation and Corrective Action Report. Complete proficiency testing policy is found on MediaLab.

**Survey Companion Document**

The Survey Companion Document accompanies all PT samples and makes it easier to track PT samples and ensures they are being tested in the appropriate manor

1. Top Section: The top section is filled out by the QA Manager or designee that processes the PT sample. This section contains the receive and due date for the PT.
2. Receipt of Shipment/Integrity of Sample: This section is completed by the QA Manager or designee that processes the PT sample. This section contains the information on whether or not the samples were received in proper condition, and any specific testing requirements in the comments.
3. Integrity, Preparation, Handling: This section is completed by the testing technologist. This section contains information on specimen integrity once the tech receives the samples. It also ensures the technologists prepares and handles the specimens correctly according to the testing instructions. If there are any issues they can be recorded in the comment section.
4. Analytical Process: This section is completed by the testing technologist. It contains information on how the specimens were tested and explains if anything unusual happened during the testing process.
5. Testing and Supervisory Documentation: This section is completed by the testing technologists and the department manager/designee. The section goal is to ensure the results transcribed onto the form are accurate compared to the raw data, all the units match, and the results were double checked by the department manager/designee. When submitting pink folders back to the QA Manager they should include (as applicable) the kit instructions, completed result form, raw data, qc record, a printout of CAP website submission.
6. Review: The document is reviewed and signed by the department Manager/Designee and the QA Manager. It is retained in the pink folder along with all of the other documentation.

**Continue on page 2**

**Survey Error Investigation and Corrective Action Report (SEICAR)**

This SEICAR is completed anytime there are “Unacceptable” results, erroneous error codes, or non-conformance events received on a PT Survey. The QA Manager collaborates with the Department Manager to complete the document.

1. Top Section: The top section is completed by the QA Manager. It is important to designate if the test is at risk and the type of non-conformance.
2. Review of testing records: This section is completed by both the Department Manager and QA Manager. The QA Manager will review all raw data to check for clerical errors and the survey companion document to ensure the test was processed correctly. The Department Manager will review for QC errors, instrument malfunctions, maintenance records, etc.
3. Previous PT Issues: This section is completed by the QA Manager. A lookback of the previous two/three survey events for the failed analyte is performed to check for trends or bias.
4. Error Code: If the SEICAR is due to an error code it can be put here, along with a description of the code.
5. Root Cause: This section is completed by both the QA Manager and the Department Manager, explaining what we determined the cause of failure to be. Root causes can be clerical, procedural, analytical, specimen handling, PT material issue, etc.
6. Patient Impact: This section is completed by both the QA Manager and the Department Manager. Depending on the root cause of the failure we must investigate patient results to ensure there was no negative impact. We can do this by checking patient records, checking qc and calibration records, re-running patient samples if available, etc.
7. Corrective Action: This section is completed by both the QA Manager and the Department Manager. If there is a corrective action needed it is explained here. For example, updating a procedure can be a corrective action.
8. Preventative Action: This section is completed by both the QA Manager and the Department Manager. What processes will be put into effect to prevent this error from happening again?
9. Follow-up: This section is completed by both the QA Manager and the Department Manager describing if any follow up needed.
10. Review: The document is reviewed and signed by the Department Manager, QA Manager, and Laboratory Director. Any print outs used in the investigation should be attached to the SEICAR, along with a copy of the unacceptable event. All portions of the form must be filled out or have “N/A”.

I have reviewed the policies and procedures above:

**Trainee Signature:­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Trainer Signature:­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_**